DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

January 20, 2015

Endochoice, Inc.
Daniel Hoefer,
Regulatory Affairs Manager
11810 Wills Rd.
Alpharetta, GA 30009

Re: K142155
Trade/Device Name: Endochoice Water Bottle Cap System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FEQ
Dated: December 9, 2014
Received: December 10, 2014

Dear Daniel Hoefer,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K142155

Device Name: Water Bottle cap system

Indications for Use

The EndoChoice water bottle cap system is intended to be used with an air source or carbon dioxide (CO_2) with the purpose of supplying sterile water to the endoscope during endoscopic procedures. It is compatible with commercially available sterile water bottles.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X	AND/OR	Over-The-Counter Use
(Part 21 CFR 801 Subpart D)		(21 CFR 801 Subpart C)

510(k) Summary
EndoChoice Water Bottle Cap System

1. Company Identification

Applicant:
EndoChoice, Inc.
11810 Wills Road
Alpharetta, GA 30009
Establishment Registration: 300759133

2. Contact Person

Daniel Hoefer
Regulatory Affairs Manager
EndoChoice, Inc.

3. Device Name

Trade name:	EndoChoice Water Bottle Cap System
Common/Usual Name:	Water bottle cap system
Classification name:	FEQ; Endoscope and Accessories

4. Device Classification

Classification	Endoscope and accessories, 21CFR 876.1500
Product Code:	FEQ
Committee:	Gastroenterology/Urology

5. Intended Use

The EndoChoice water bottle cap system is intended to be used with an air or CO_2 source from an endoscope with the purpose of supplying sterile water to the endoscope during endoscopic procedures. It is compatible with commercially available sterile water bottles.

6. Device Description

The EndoChoice water bottle cap system is a sterile disposable device designed to fit commercially available sterile water bottles for providing sterile water during endoscopic procedures. The water bottle cap system is designed with a clip that is placed on the tubing to stop water flow from the water bottle when the endoscope is not in use.

The device attaches via a connector to the air/water port of an endoscope. The water bottle cap itself is attached to a standard sterile water bottle. Air supplied from the processor unit then pressurizes the water bottle, providing water flow when then air/water valve of the endoscope is depressed. Some models provide a feature that provides an option to use a CO_2 air source. Instructions state that the device is to be used by trained endoscopy professionals.

7. Substantial Equivalence

The modified EndoChoice Water Bottle Cap System is substantially equivalent to the legally marketed Aquashield system CO_2 (K120123, United States Endoscopy). A feature comparison of the two devices is shown below.

Based on the intended use, technological characteristics and overall performance of the devices, EndoChoice, Inc. believes that the *EndoChoice water bottle cap system* is substantially equivalent to the predicate and that the differences between the devices do not raise new issues of safety or effectiveness.

Comparison Table		
	Aquashield System CO_2	**EndoChoice Water Bottle Cap System**
510(k) number	K120123	142155
Manufacturer	United States Endoscopy	EndoChoice, Inc.
Compatibility with currently available endoscopes	Olympus 140, 160, 180 and 190 Endoscopes	Olympus 140, 160, 180 And Fuse Endoscopes
Sterilization	Provided sterile	Provided sterile via Ethylene Oxide
Compatibility with commercially available sterile water bottles	Compatible with standard commercially available sterile water bottles	Same
Indications for use statement	The Aquashield System CO_2 is intended to be used with an air or carbon dioxide (CO_2) source with the purpose of supplying sterile water to the endoscope during endoscopic procedure. It is compatible with U.S. commercially available sterile water bottles.	The EndoChoice water bottle cap system is intended to be used with an air source or carbon dioxide (CO_2) with the purpose of supplying sterile water to the endoscope during endoscopic procedures. It is compatible with U.S. commercially available sterile water bottles.
Contraindications	Those specific to any endoscopic procedure	Those specific to any endoscopic procedure
Materials (patient contacting)	PC-1100,Stainless Steel, PVC	PC-1100, Stainless Steel, PVC, TPE 8597N
Materials (no patient contact)	Polymers, PVC, stainless steel	TPE-2102-501, Polypropylene Y2600, HDPE 530 ST, LDPE 2426H, Adhesive Paper, NBR
Packaging	Individually packaged in Tyvek Peel Pouch	Individually packaged in Tyvek Peel Pouch
Use	Disposable, maximum use 24 hours	Disposable, maximum use 24 hours

8. Non-clinical testing

Non-clinical testing has been performed on the device. Specifically, the following has been completed on the water bottle cap and tubing set:

- Benchtop functional performance testing
- Laboratory validation testing of sterilization
- Biocompatibility testing in conformance with ISO 10993-1.

All test results passed, demonstrating that the device is safe and effective in comparison with the predicate device.

9. Conclusion

The modified EndoChoice Water Bottle Cap System is equivalent to the legally marketed predicate device. It is the same or equivalent in terms of design, intended use, materials, and labeling.